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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,241	02/27/2002	Takuya Watanabe	57132 (46342)	2935

21874 7590 12/17/2003

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EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,241	WATANABE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8,10,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/27/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2/17,3/5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I, claims 1-7, 9, 11, and 14, on August 29, 2003 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

   The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' amendments filed on 1/1/2003 and 8/29/2003 have been entered in full. Claims 1-14 are pending. Claims 1-7, 9, 11, and 14 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

4. The drawings filed on 2/27/2003 are accepted the Examiner.

Information Disclosure Statement

5. The Information Disclosure Statements submitted on 2/27/2002 and 3/5/2003 have been received by the Office. The references listed in PTO-1449 forms have been fully considered by the Examiner.

Rejections—35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-4, 11, and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, a protein of SEQ ID NO: 1, a DNA encoding the protein. Since these molecules can be found in nature, the claims read on a product of nature. Products of nature do not constitute statutory subject matter. It is suggested that the word "isolated" or "purified" be used to amend the claims to overcome this rejection.

9. Claims 1-7, 9, 11, and 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-7, 9, 11, and 14 are drawn to a protein comprising SEQ ID NO: 1 or its homologues, a DNA encoding the proteins, a method of producing the proteins, and a method of determining a ligand to the proteins. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter

claimed and that identifies a "real world" context of use for the claimed invention which does not requires further research.

The specification asserts that the present invention relates to a human brain-derived G protein coupled receptor (GPCR; lines 7-9 of page 1). The specification discloses the expression of the protein of SEQ ID NO: 1 in various tissues (Example 2), which shows high expression in the heart, kidney, and testis (Fig. 4 and Table 1). Nonetheless, the specification fails to disclose the biological functions or any physiological significance of the protein of SEQ ID NO: 1 or the DNA encoding the protein. The specification fails to disclose a specific and substantial utility for the claimed invention.

The specification further asserts that the protein of the present invention and the DNA encoding the protein are useful for the prevention and/or treatment of a list of numerous diseases (the middle of page 55) and the cDNA of the present invention is useful as a gene diagnostic agent (bottom of page 58). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed protein and DNA nor any diseases that are associated with the claimed molecules. Clearly, further research would be required to determine the functions of the claimed molecules or to identify a disease that can be treated or diagnosed with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. While the specification asserts that the present invention is related to a human GPCR, there is no sufficient evidence indicating that the protein of the present invention is a truly functional GPCR. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the compounds.

10. Claims 1-7, 9, 11, and 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

Furthermore, even if the protein of SEQ ID NO: 1 or the DNA of SEQ ID NO: 2 that encodes SEQ ID NO: 1 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 recites a protein which comprises the same or substantially the same amino acid sequence SEQ ID NO: 1, whereas claim 2 recites a partial peptide of the protein of claim 1. Claims 3 and 14 recite a DNA that encodes the protein of claim 1 or hybridises to the DNA encoding the protein of claim 1. However, other than the protein of SEQ ID NO: 1 and the DNA of SEQ ID NO: 2 that encodes the protein, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claim. The disclosure has not shown (i) which portions of SEQ ID NO: 1 or SEQ ID NO: 2 are critical to the activity of the protein of SEQ ID NO: 1; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 1 will result in protein mutants with the same functions as the protein of SEQ ID NO: 1. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Accordingly, the disclosure fails to enable such a myriad of the claimed protein and DNA molecules that not only vary substantially in length but also in amino acid/nucleic acid composition and fail to provide any guidance to those skilled generally on how to make and use the genus of protein and DNA molecules. Thus, it would require undue experimentation for one skilled in the art to make and use the

claimed genus of protein and DNA molecules embraced by the instant claims.

Claim Rejections—35 USC § 112, 1st paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-3, 5-7, 9, 11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification discloses a protein of SEQ ID NO: 1 and a nucleic acid sequence of SEQ ID NO: 2 that encodes the protein of SEQ ID NO: 1. However, claims 1 and 2 recites the protein of SEQ ID NO: 1 and its homologues and fragments, whereas claims 3 and 14 recite a DNA that encodes the protein of claim 1 or hybridises to the DNA encoding the protein of claim 1. Claims 5-7, 9, and 11 depend, either directly or indirectly, from claim 1. The claims do not require that the proteins and nucleic acids possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of protein and its homologues or a genus of DNA molecules.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of

complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in claim 1 and 2 is a partial structure in the form of a recitation of "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1". The specification asserts that the substantially the same amino acid sequence includes an amino acid sequence having at least about 50% homology, preferably at least 70% homology, more preferably at least 80% homology...." (pages 13 and 16 of the specification). Likewise, the only factor present in claim 14 is a mere chemical property of the DNA in the form of a recitation of 'hybridize to DNA encoding the protein of SEQ ID NO: 1 or its homologues. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, only the protein of SEQ ID NO: 1 and the DNA encoding the protein (including SEQ ID NO: 2), but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections—35 USC § 112, 2nd paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-3, 5-7, 9, 11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites the term "substantially the same". Since neither the art nor the specification provides an unambiguous definition for the term, the claim is indefinite.

Claim 9 provides for the use of the protein of claim 1, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 14 is indefinite because it recites "under highly stringent conditions", but without giving the conditions in the claim. Since neither the art nor the specification provides an unambiguous definition for the term, the claim is indefinite.

Claims 2, 3, 5-7, and 11 depend, either directly or indirectly, from claim 1.

Claim Rejections—35 USC § 102 (e)

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in
>
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,
>
> except that an international application filed under the treaty defined in section 351() shall have the effects for the purpose of this subsection of an application filed in the Unites States only if the international application designated the Unites states and was published under Article 21(2) of such treaty in the English.

15. Claims 1-7, 9, 11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2003/0148450 A1, published on August 8, 2003; priority date, February 26, 1999).

Chen et al. teach a human orphan G protein coupled receptor with an amino acid sequence being 99.9% identical to SEQ ID NO: 1 and the cDNA that encodes the receptor protein (see attached sequence alignment). This cDNA, which has 53.6% match with SEQ ID NO: 2 (from nucleotide No. 354 to nucleotide No. 1649) with 99.9% similarity, would hybridize to SEQ ID NO: 2. Chen et al. also teach a vector and a host cell comprising the cDNA that encodes the receptor protein, as well as a method of producing the receptor protein (see, e.g., claims 73-76; Example 2). Thus, the reference of Chen et al. meets the limitations of claims 1-7, 9, 11, and 14.

Claim Objections

16. Claims 7, 9, and 11 are objected to under 37 CFR 1.75(c) as being in improper multiple dependent form because a multiple dependent claim should refer back to a preceding claim in the alternative only. See MPEP § 608.01(n).

17. The prior art made of record in PTO-892 form and not relied upon is considered pertinent to applicant's disclosure.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.

This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
December 8, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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